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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,685	11/07/2000	Julio C. Palmaz	6006-015	9696

7590 08/05/2004

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EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/707,685	PALMAZ ET AL.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The substitute specification, filed July 9, 2004, including amendments incorporating subject matter previously incorporated by reference to US Patent 6,379,383 B1 has been accepted.

Response to Arguments

Applicant's arguments with respect to claims 39-66 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 39-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitcher et al. (Pub.No. US 2003/0018381 A1, cited in previous office action). Referring to claim 39, Whitcher discloses a method of manufacturing an endoluminal stent (100) capable of radially expanding from a first diameter to a second diameter and having a plurality of first and second structural elements (fig.2), defining a longitudinal axis and circumferential axis of the stent comprising the steps of vacuum depositing a stent forming metal (120) onto an unpatterned, exterior surface of a generally cylindrical substrate (105) at a deposition rate ([0035]. >0.05 mm/min) that controls a

formation of heterogeneities [0028], (a deposition rate is disclosed, therefore, heterogeneities inherently are formed, since all applicant has claimed it a deposition rate) to form a generally tubular, unpatterned, *substantially* homogeneous (film is of uniform thickness as shown in fig.5; precisely controls thickness and composition, [0028, 0048]) metal film (115), defining the plurality of first and second structural elements of the stent in the unpatterned metal film, and removing the stent from the substrate [0051, 0052, 0053].

Referring to claim 40, Whitcher discloses depositing a sacrificial material layer (130) onto the substrate (105) prior to vacuum deposition and removing the sacrificial layer in order to remove the stent from the substrate [0053].

Referring to claims 41-45, Whitcher discloses vacuum deposition by ion beam assisted evaporation, sputtering, in the presence of an inert gas [0034, 0035, 0036, 0037].

Referring to claim 45, Whitcher discloses a deposition rate no less than 20 nm/sec ([0035], > 0.05 mm/min).

Referring to claim 46, Whitcher discloses rotation of the substrate during deposition ([0035], rotate or translate the substrate).

Referring to claims 47 and 54, Whitcher discloses a method of making an endoluminal stent (100) comprising vacuum depositing [0034, 0035, 0036, 0037] nickel and titanium [0062] onto an exterior surface of a generally cylindrical substrate (105) to form a generally tubular, substantially homogeneous (film is of uniform thickness as shown in fig.5; precisely controls thickness and composition, [0028, 0048]) film of nickel-titanium having no less than about 51.5 atomic percent nickel [0066], table 1, and removing the stent from the substrate [0051, 0052, 0053].

Referring to claims 48, 50, and 51, Whitcher discloses a nickel-titanium composition between *about* 51.5 and 55.0 atomic percent nickel, wherein the nickel and titanium is a binary nickel-titanium alloy (table 1), [0062, 0066].

Referring to claim 49, Whitcher discloses the rotation of the substrate during deposition (vector A, [0048]).

Referring to claims 52 and 53, Whitcher discloses imparting a pattern onto the exterior surface of the substrate (105), wherein the pattern is transferred to the film during deposition [0055, 0056], and alternatively, imparting a pattern onto the tubular film after deposition [0054].

Referring to claim 55, Whitcher discloses depositing a sacrificial material layer (130) onto the substrate (105) prior to vacuum deposition and removing the sacrificial layer in order to remove the stent from the substrate [0053].

Referring to claims 55-56, Whitcher discloses vacuum deposition by ion beam assisted evaporation, sputtering, in the presence of an inert gas [0034, 0035, 0036, 0037].

Referring to claim 58, Whitcher discloses a deposition rate no less than about 20 nm/sec [0035].

Referring to claim 59, Whitcher discloses a method of making an implantable medical device (100) comprising vacuum depositing [0034, 0035, 0036, 0037] a device-forming metal (120) onto an exterior surface of a substrate (105) under a condition that controls a formation of heterogeneities [0028] (Whitcher discloses a condition, which is all applicant has claimed, the condition inherently having control over heterogeneities) to form a substantially homogeneous (film is of uniform thickness as shown in fig.5; precisely controls thickness and composition,

[0028, 0048]) metal film (115) and removing the implantable medical device from the substrate [0051, 0052, 0053].

Referring to claims 60-61, Whitcher discloses imparting a pattern onto the exterior surface of the substrate prior to step a.[0055, 0056], and imparting a pattern defining the first and second structural elements onto the metal film after step a [0054].

Referring to claim 63, Whitcher discloses controlling the deposition rate during step a [0035], rate being 0.05 mm/min.

Referring to claims 62 and 64-65, Whitcher discloses control of formation of heterogeneities, including polar and non-polar binding sites, grain size, grain phase, grain material composition, material composition, and surface topography, and rotation of the substrate during deposition [0028].

Referring to claim 66, Whitcher discloses a metal film (115) comprising no less than about 51.5 atomic percent nickel (table 1), [0066].

Claims 39-40, 42, 46-57, and 59-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al. (USPN 6,533,905 B2, cited in previous office action). Referring to claim 39, Johnson discloses a method of manufacturing an endoluminal stent capable of radially expanding from a first diameter to a second diameter and having a plurality of first and second structural elements (fig.9; col.1, lines 10-15), defining a longitudinal axis and circumferential axis of the stent comprising the steps of vacuum depositing (col.4, lines 52-53; col.5, lines 19-20) a stent forming metal onto an unpatterned, substantially homogeneous (uniform deposition, uniform thickness, fig.1b; composition and thickness precisely controlled, col.2, lines 14-20, 29-

31, 36-39; col.4, lines 54-65; col.5, lines 43-47) exterior surface of a generally cylindrical substrate (10; col.3, lines 62-67) at a deposition rate that controls a formation of heterogeneities (every rate has control over heterogeneities) to form a generally tubular, unpatterned metal film, defining the plurality of first and second structural elements of the stent in the unpatterned metal film, and removing the stent from the substrate (col.4, lines 21-31; col.5, lines 62-67).

Referring to claim 40, Johnson discloses depositing a sacrificial material layer (14) onto the substrate (10) prior to vacuum deposition and removing the sacrificial layer in order to remove the stent from the substrate (col.4, lines 24-31).

Referring to claim 42, Johnson discloses vacuum deposition by sputtering (col.5, lines 25-29).

Referring to claim 46, Johnson discloses rotation of the substrate during deposition (col.4, lines 48-53).

Referring to claims 47 and 54, Johnson discloses a method of making an endoluminal stent (fig.9) comprising vacuum depositing nickel and titanium (col.4, lines 54-65; col.3, lines 25-29) onto an exterior surface of a generally cylindrical substrate (10) to form a generally tubular, substantially homogeneous (uniform deposition, uniform thickness, fig.1b; composition and thickness precisely controlled, col.2, lines 14-20, 29-31, 36-39; col.4, lines 54-65; col.5, lines 43-47) film of nickel-titanium having no less than about 51.5 atomic percent nickel (col.4, lines 54-65; col.3, lines 25-29; col.5, lines 1-13) and removing the stent from the substrate (col.5, lines 62-67).

Referring to claims 48, 50, and 51, Johnson discloses a nickel-titanium composition between about 51.5 and 55.0 atomic percent nickel, wherein the nickel and titanium is a binary nickel-titanium alloy (col.4, lines 54-65; col.3, lines 25-29; col.5, lines 1-13).

Referring to claim 49, Johnson discloses the rotation of the substrate during deposition (col.4, lines 48-53).

Referring to claims 52 and 53, Johnson discloses imparting a pattern onto the exterior surface of the substrate (col.6, lines 36-50), wherein the pattern is transferred to the film during deposition, and alternatively, imparting a pattern onto the tubular film after deposition (col.6, lines 19-22).

Referring to claim 55, Johnson discloses depositing a sacrificial material layer (14) onto the substrate prior to vacuum deposition and removing the sacrificial layer in order to remove the stent from the substrate (col.4, lines 25-31; col.5, lines 61-67).

Referring to claims 55-56, Johnson discloses vacuum deposition by sputtering, in the presence of an inert gas (col.5, lines 25-31).

Referring to claim 59, Johnson discloses a method of making an implantable medical device comprising vacuum depositing a device-forming metal onto an exterior surface of a substrate (col.5, lines 25-33) under a condition (condition being material selection, pressure, deposition rate, col.5, lines 25-30, which is controlled, col.4, lines 54-65) that controls a formation of heterogeneities (inherently controlled, see response to arguments above) to form a substantially homogeneous (uniform deposition, uniform thickness, fig.1b; composition and thickness precisely controlled, col.2, lines 14-20, 29-31, 36-39; col.4, lines 54-65; col.5, lines 43-

47) metal film and removing the implantable medical device from the substrate (col.5, lines 62-67).

Referring to claims 60-61, Johnson discloses imparting a pattern onto the exterior surface of the substrate prior to step a. (col.6, lines 36-50), and imparting a pattern defining the first and second structural elements onto the metal film after step a (col.6, lines 19-22).

Referring to claim 63, Johnson discloses controlling the deposition rate during step a (col.5, lines 25-30, sputter deposition is carried out, since deposition is conducted, inherently it is deposited at a rate).

Referring to claims 62 and 64-65, Johnson discloses control of formation of heterogeneities (a condition is chosen, and the condition has control over the heterogeneities inherently, also, Johnson discloses precisely controlling the composition, col.4 line 54-col.5 line 13), including polar and non-polar binding sites, grain size, grain phase, grain material composition, material composition, and surface topography, and rotation of the substrate during deposition.

Referring to claim 66, Johnson discloses a metal film comprising no less than about 51.5 atomic percent nickel (col.4 line 54-col.5 line 13).

Claims 59-61 and 63-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Clubb et al. (USPN 6,203,732 B1, cited in previous office action). Referring to claim 59, Clubb discloses a method of manufacturing an implantable medical device (100; col.1, lines 6-10) capable of radially expanding from a first to a second diameter, having a plurality of first structural elements (104) defining a longitudinal axis of the device and a plurality of second

structural elements (106) interconnecting adjacent pairs of the first structural elements and defining a circumferential axis of the device, (fig.17) comprising the steps of vacuum depositing (col.4, lines 39-41; col.5, lines 35-47) a device forming metal (20) onto an exterior surface (12) of a substrate (10) under a condition that controls a formation of heterogeneities (it is noted to the applicant that all the applicant has claimed here is a **condition**. Every condition is a variable, such as deposition rate, temperature, pressure, choice of material, etc, and each condition/variable will have an effect on the heterogeneity of the material, therefore, every condition controls the formation of heterogeneities. Even if no heterogeneities are present, a condition still controls it, to the degree of zero, in essence, the applicant has only a condition, and during deposition, a *condition* is always present. Also, every material has a specific grain size, grain phase, composition, and binding sites, and just by the user selecting a specific material, the user is controlling the grain size, grain phase, composition, binding sites (heterogeneities), by selection of a material with the desired properties), (it is further noted to the applicant, that Clubb not only discloses a deposition condition, col.5, lines 35-46, but also discloses formation of various material compositions, and material topographies, col.5, lines 10-20, which the applicant claims to be examples of heterogeneities) to form a substantially homogeneous (fig.14 has shown a film layer, which is shown as a uniform thickness, therefore homogeneous, discloses a layer, col.4, lines 39-41, layer defined in its broadest definition, as one thickness, also, composition is controlled, col.5, lines 10-20) metal film, and removing the implantable medical device (100) from the substrate (10), (col.4, lines 54-60).

Referring to claims 60-61, Clubb discloses imparting a pattern (100c) onto the exterior surface (12) of the substrate (10) prior to step a. (col.3, lines 48-55), and imparting a pattern

(104, 106, by removing excess material of 20) defining the first and second structural elements onto the metal film (20) after step a (col.4, lines 44-53).

Referring to claim 63, Clubb discloses controlling the deposition rate during step a (Clubb discloses deposition, col.4, lines 39-41; col.5, lines 35-46, and because deposition is occurring, it is inherently occurring at some rate, and the rate used, has been controlled by the user. The user has controlled the rate by selecting a rate, inherently the rate is controlled).

Referring to claims 64-65, Clubb discloses control of formation of heterogeneities, including polar and non-polar binding sites, grain size, grain phase, grain material composition, material composition, and surface topography (Clubb discloses choosing combinations of materials, (material composition), and choosing various topographies (col.5, lines 10-20), and by choice of these factors, the user has control over the grain size, phase, and binding sites, which are properties of the material, (which the user has chosen, therefore, the control of formation of heterogeneities are inherently controlled)).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cheryl Miller

BRUCE SNOW
PRIMARY EXAMINER